

David Wynn (DW 8660)
ARENT FOX LLP
1675 Broadway
New York, NY 10019
(212) 484-3900
FAX (212) 484-3990

Attorneys for Plaintiff
ORGANOGENESIS, INC.

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ORGANOGENESIS, INC.,

Plaintiff,

-against-

ADVANCED BIOHEALING, INC.,

Defendant.

Civil Action No. 08 CV 00875(AKH)
Hon.

**Declaration of Savalle C. Sims in
Support of Motion for Temporary
Restraining Order, Preliminary
Injunction and Expedited Discovery**

I, Savalle C. Sims, do depose and state:

1. I am a member in good standing of the Bars of the State of Maryland, the Commonwealth of Virginia, and the District of Columbia, and several federal courts.
2. I have personal knowledge of the facts set forth herein, except for those stated to be upon information and belief, and if called as a witness, would and could competently testify thereto under oath.
3. I am a member of the law firm of Arent Fox LLP, attorneys for the Plaintiff Organogenesis, Inc. ("OI") in the above-referenced action. I submit this declaration in support of OI's request for relief, brought by Order to Show Cause with Temporary Restraining Order, and for a preliminary injunction in the above-captioned action (the "Application"), and to place into the record certain facts, pleadings, and documentation in support of the Application.

4. OI has respectfully moved for a temporary restraining order and an order preliminarily enjoining Defendant Advanced BioHealing, Inc. (“Defendant” or “Advanced BioHealing”) from disseminating false, malicious and defamatory advertising directed to OI’s customers and potential customers.

5. This Application is made on the grounds that Advanced BioHealing will, unless restrained, continue to send communications to OI’s customers and potential customers that contain false and defamatory information regarding OI’s Apligraf® product (“Apligraf”) and OI’s recent recall regarding Apligraf and to interfere with OI’s recall.

6. As discussed and described in more detail in the Complaint filed in this matter and the Declaration of Patrick Bilbo, OI’s Vice President of Regulatory Affairs, Advanced BioHealing has disseminated, and upon information and belief, continues to disseminate a product recall letter prepared by OI to OI’s customers and potential customers, while at the same time falsely and misleadingly advertising the purported benefits of Advanced BioHealing’s competing product.

7. As discussed and described and Mr. Bilbo’s Declaration, Apligraf was the subject of a very limited recall involving 177 Apligraf units (the “Apligraf Recall”). On or about January 9, 2008, OI discovered that its competitor, Advanced BioHealing, had disseminated an electronic mail message to an Apligraf customer in New York attaching OI’s product recall letter, while at the same time falsely and misleadingly advertising Advanced BioHealing’s competing product and denigrating Apligraf.

8. Upon learning of the Advanced BioHealing Communication, OI immediately advised Advanced BioHealing of the false claims contained in the Advanced BioHealing Communication and requested that Advanced BioHealing stop further dissemination of the

Advanced BioHealing Communication. More specifically, OI's counsel sent a letter to Advanced BioHealing's Chief Executive Officer, Kevin Rakin. A copy of OI's counsel's letter to Mr. Rakin is attached hereto as Exhibit 1.

9. Initially, Advanced BioHealing stated, through its counsel, that it would investigate OI's claims. A copy of Advanced BioHealing's response is attached hereto as Exhibit 2.

10. On or about January 14, 2008, the parties began discussing the possibility of settlement regarding the matters raised in OI's letter to Advanced BioHealing dated January 9, 2008. At that time, Advanced BioHealing, through counsel, indicated that Advanced BioHealing had ceased disseminating communications regarding the Apligraf Recall as of January 9 or 10, 2008, and would continue to do so while the parties' discussed the possibility of settlement.

11. On or about January 16, 2008, however, OI learned that Advanced BioHealing may not have ceased disseminating communications regarding the Apligraf Recall. OI informed me that one of its customers sent OI an electronic mail communication from Advanced BioHealing dated January 14, 2008.

12. Counsel for OI promptly contacted Advanced BioHealing's counsel and notified him of the additional Advanced BioHealing Communication and requested assurances that Advanced BioHealing had ceased disseminating communications regarding Apligraf and the Apligraf Recall. Letter to Charles Tobin, Esquire dated January 16, 2008 is attached hereto as Exhibit 3.

13. In response, Advanced BioHealing's counsel *now* assured OI, in writing, that Advanced BioHealing notified its sales force to cease sending communications regarding the Apligraf Recall as of January 11, 2008 not January 9 or 10, 2008 as had been previously

represented. A copy of an electronic mail message from Charles Tobin, Esquire to Savalle C. Sims, Esquire is attached as Exhibit 4.

14. On January 18, 2008, OI informed counsel that it had learned definitively that Advanced BioHealing had not ceased disseminating communications regarding the Apligraf Recall as of January 9, 10 or 11, 2008 despite Advanced BioHealing's representations to the contrary. More specifically, OI informed counsel that it learned that on or about January 14, 2008, Advanced BioHealing sent out an electronic mail communication to OI's customers and other wound-care providers regarding Apligraf and the Apligraf Recall.

15. Despite assurances to the contrary, Advanced BioHealing has not ceased disseminating communications regarding Apligraf or the Apligraf Recall, necessitating the need for an immediate temporary restraining order.

16. OI is being irreparably harmed and will continue to be irreparably harmed unless Advanced BioHealing's unlawful activities are immediately enjoined. Advanced BioHealing's actions have unnecessarily expanded the scope of the Apligraf Recall and interfered with the administration of the Apligraf Recall. Advanced BioHealing's conduct has jeopardized public safety and health. Advanced BioHealing's actions have also potentially harmed the Apligraf Brand.

17. Issuance of a temporary restraining order is particularly appropriate here because OI and Advanced BioHealing are direct competitors, and Advanced BioHealing's communications mention Apligraf by name. As discussed, in the memorandum in support of the Application, in the Second Circuit, irreparable harm is presumed where a plaintiff demonstrates a likelihood of success in showing a literally false comparative advertisement mentions plaintiff's product by name. Moreover, where, as here, the defendant makes false

deceptive claims, to OI's customers or to other physicians or wound-care providers.

Specifically, OI seeks the following documents and information:

- the names and contact information for all agents, employees or other individuals acting on behalf of Advanced BioHealing who sent, transmitted or communicated the Advanced BioHealing Communication and/or the Additional Advanced BioHealing Communication to any individuals and any responses received;
- the names and contact information of all individuals or entities to whom Advanced BioHealing sent, transmitted or communicated the Advanced BioHealing Communication and/or the Additional Advanced BioHealing Communication and any responses received;
- the names and contact information of all individuals or entities to whom Advanced BioHealing sent, transmitted or communication any information regarding the Apligraf Recall or the Apligraf Recall Letter and any responses received;
- Copies of all communications sent by Advanced BioHealing to wound-care providers regarding the Apligraf Recall or the Apligraf Recall Letter and any responses received;
- the names and contact information of any OI customers or wound-care providers who were contacted in-person or orally by Advanced BioHealing regarding the Apligraf Recall and the Apligraf Recall Letter.

23. OI also seeks to take the 30(b)(6) deposition of Advanced BioHealing's corporate designee regarding the documents that are produced and the communications disseminated by Advanced BioHealing regarding Apligraf and the Apligraf Recall and any responses received.

24. Until OI has discovery from Advanced BioHealing on these issues, the full extent of harm and damage caused by Advanced BioHealing's deceptions and false statements will not be known.

25. This action is being filed today on behalf of OI, and no prior requests for this relief have been filed.

Pursuant to 28 U.S.C. § 1746, I declare under the penalties of perjury that the foregoing declaration is true and correct.

Executed on: January 24, 2008


Savalle C. Sims

Sworn To Before Me This
24th Day of January 2008


Notary Public

David N. Wynn
Notary Public, State of New York
No. 02WY4770880
Qualified in New York County
Commission Expires Nov. 30, 2010

Exhibit 1

Arent Fox LLP / Washington, DC / New York, NY / Los Angeles, CA

Arent Fox

James R. Ravitz

Attorney

202.857.8903 DIRECT

202.857.6395 FAX

ravitz.james@arentfox.com

January 9, 2008

VIA FACSIMILE AND FEDERAL EXPRESS

Mr. Kevin Rakin
Chief Executive Officer
Advanced BioHealing, Inc.
Suite 200
10933 North Torrey Pines Road
La Jolla, CA 92037

Re: Apligraf®

Dear Mr. Rakin,

This firm represents Organogenesis, Inc. (OI). As you are undoubtedly aware, OI is the manufacturer, distributor, and owner of all rights in Apligraf® (Apligraf), an advanced wound healing product. As you also know, OI is currently undertaking a relatively limited recall regarding certain Apligraf units (the Apligraf Recall).

OI recently learned, through numerous reports from physicians that Advanced BioHealing, Inc. (ABH) has sent at least one improper and unlawful written communication regarding Apligraf to a number of physicians. We refer, in particular, to the enclosed electronic mail message (with attachment) that Andrew Sole, an ABH sales representative, sent to an undisclosed number of recipients on January 8, 2008 (the ABH Communication). We assume that the ABH Communication was sent not only to physicians who currently use Apligraf, but also to all physicians who treat wounds. In addition, we have received other similar reports across the country concerning verbal statements by ABH to physicians along the same lines as the ABH Communication.

The ABH Communication is clearly designed to unlawfully denigrate Apligraf, unlawfully promote ABH's product Dermagraft, unlawfully interfere with OI's current and prospective business relationships, and improperly interfere with the Apligraf Recall. This

Mr. Kevin Rakin
January 9, 2008
Page 2

Arent Fox

intention is evidenced by the false, disparaging, and defamatory statements contained in the ABH Communication that we believe violate not only the Federal Food, Drug, and Cosmetic Act, but also various federal and state advertising laws. For instance, the ABH Communication implies that OI is concealing the Apligraf Recall from its customers and failing to conduct the Apligraf Recall in a compliant manner. This is misleading, false and disparaging.

ABH's statements regarding the alleged advantages of cryo-preservation over Apligraf with respect to potential contamination are also misleading and false. In addition to the 1998 Dermagraft recall for endotoxin contamination, the Food and Drug Administration's (FDA) MAUDE database reflects numerous instances of cases where people treated with Dermagraft developed post-implantation complications from the implant. Further, ABH's statement that "Dermagraft goes through 14 day sterility testing by the FDA before it is shipped" is also false. As you undoubtedly are aware, the FDA does not conduct sterility testing or any type of testing for that matter. Such statements are clearly designed and intended to negatively impact OI by misleading physicians into believing that the FDA is involved in the Dermagraft manufacturing process, and that Apligraf, in general, fails to meet FDA standards.

Additionally, ABH's statements that cryo-preservation "allows for safety testing prior to shipping and application" implies that Apligraf is not safety tested prior to release. This is not only false but is disparaging to OI and Apligraf.

Moreover, ABH's actions, which are designed to interfere with OI's ongoing and prospective business relationships, are interfering with OI's ability to conduct the Apligraf Recall. OI is working closely with the FDA to ensure that the Apligraf Recall is conducted in an appropriate and compliant manner. As a result of ABH's actions, however, OI has received several signed recall communications from physicians who did not receive the affected Apligraf unit. Based on information available to us, we believe that those physicians received the recall communication from ABH and were confused as to their responsibilities regarding the Apligraf Recall. Such interference is making it difficult for OI to properly implement and track the effectiveness of the recall. Thus, ABH's actions are significantly negatively impacting the effectiveness of the Apligraf Recall which creates a serious risk to the public health.

Accordingly, OI demands that ABH immediately cease and desist from interfering with the Apligraf Recall and from making any further false, disparaging, or defamatory statements regarding Apligraf; and that you confirm in writing no later than January 11, 2008, that you will cease your recent activities described herein. We further demand that you provide us with a list of all physicians and wound centers to which the ABH Communication was distributed. In the event that you fail to comply with these demands, OI reserves the right to pursue all legal remedies at its disposal to address ABH's activities. Notwithstanding, OI intends to notify the

Mr. Kevin Rakin
January 9, 2008
Page 3

Arent Fox

FDA regarding ABH's recent activities so that steps can be taken to minimize the harm that ABH has already caused to the Apligraf Recall from a public health standpoint.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Ravitz', with a long horizontal flourish extending to the right.

James R. Ravitz

Enclosure

cc: Mr. Geoff MacKay
Mr. Patrick R. Bilbo
Organogenesis, Inc.
✓ Savalle Sims, Esq.
Arent Fox LLP

Attachments: 20080107053634.pdf



20080107053634.p
df (57 KB)

-----Original Message-----

From: "Andrew Sole" <asole@advancedbiohealing.com>

Date: Tue, 8 Jan 2008 20:30:42

To: undisclosed-recipients;

Subject: Apligraf Recall Letter

Wound Care Provider,

I am sending a safety notification to all wound care providers that use multiple advanced wound care products in their practice. (Letter attached) This letter was sent directly from Organogenesis to many of their Apligraf customers throughout the country, but evidently not everyone. The letter outlines specific instructions to the physician. I am sending this letter in hopes that none of the contaminated Apligraf was applied to your patients.

A reminder Dermagraft is the only cyro-preserved human-derived dermal substrate available. The advantages of cyro-preservation over the rest of the products out there are countless. Most importantly, Dermagraft goes through 14 day sterile testing by the FDA before it is shipped. This leaves no chance for contamination and 100% confidence in safety for your patients' wounds.

Proprietary cryopreservation process ensures confidence

Dermagraft is cryopreserved to allow long-term maintenance of tissue integrity and cellular viability.

Cryopreservation of Dermagraft offers a number of additional product benefits:

- Allows for safety testing prior to shipping and application
 - Provides longer shelf life—long-term storage (up to 6 months) when stored at $-75^{\circ}\text{C} \pm 10^{\circ}\text{C}$
- There have been no reported immunological responses or rejections from patients that received Dermagraft.

Andrew Sole
Advanced Technology Specialist-New York
Advanced BioHealing, Inc.
Direct: 732 991-3610
Email: asole@advancedbiohealing.com
Orders: 1-877-DERMAGRAFT (877-337-6247)

Organogenesis Inc.

LIVING TECHNOLOGY

150 Dan Road, Canton, Massachusetts 02021

December 27, 2007

Subject: Potential contaminated Apligraf Units manufactured by Organogenesis Inc.

Dear Doctor:

This letter is intended to inform you of important information regarding Apligraf units shipped to you on December 14 or 17, 2007. This involves units from Apligraf Lot Number GS0711.20.01.2A. You have received Apligraf unit(s) from this Lot.

Description of Issue

Apligraf Lot Number GS0711.20.01.2A was reported to have contamination in the agarose nutrient medium of some units retained at Organogenesis. Colonies were visually observed within the agarose. Preliminary microbiological testing identified the bacterial contaminant as a gram positive rod (bacillus) organism. A definitive identification of the organism will be provided to you by fax as soon as available.

Product Disposition

According to our records, your procedure date(s) for Apligraf from this Lot has already occurred and the product has likely been applied to a patient(s). If you have not applied the affected unit(s) to a patient, you should return unused product to Organogenesis Inc. for investigation. Information on product return can be obtained by contacting Organogenesis at the number below. Please maintain accurate and complete records of all returns and their disposition.

Clinical Implications

While the unit(s) you have received may not be contaminated, all standard wound care precautions should be used to assure the safety of the patient. If the affected units had been applied to a patient, it is recommended that you monitor the patient closely for any potential adverse events. Organogenesis recommends careful assessment of possible infection by observing for signs and symptoms of infection as well as treatment per your clinical discretion. Treatment options at your clinical

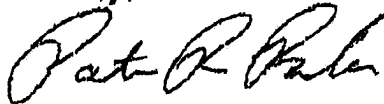
discretion include topical antibiotics, oral antibiotics or Apligraf removal. We hope that this information is helpful in managing care for your patient.

The quality of Apligraf and its safety are of the highest priority to Organogenesis. We are committed to providing complete information in a timely fashion and will contact you for patient follow up and reports of any adverse events that may have resulted subsequent to this Apligraf treatment.

In addition to this faxed letter, we are attempting to contact you by phone to provide information on this Apligraf Lot. Although we will be attempting to contact you by phone today, it will be most efficient if you can contact us at 1 888 432-5132, Option # 2 (Medical Inquiries).

To confirm receipt of this important communication, please sign and fax back this form to us at 781-401-1288.

Sincerely,



Patrick Bilbo
Vice President, Regulatory Affairs
(781) 401-1155

Recipient Signature: _____

Recipient Name: _____

PLEASE RETURN THIS LETTER SIGNED TO FAX #781-401-1288

Exhibit 2

Holland & Knight

Tel 202 955 3000
Fax 202 955 5564

Holland & Knight LLP
2099 Pennsylvania Avenue, N.W., Suite 100
Washington, D.C. 20006-6801
www.hklaw.com

CHARLES D. TOBIN
(202) 419-2539
ctobin@hklaw.com

January 11, 2008

Via Facsimile And U.S. Mail

James R. Ravitz, Esq.
Arent Fox LLP
1050 Connecticut Avenue, N.W.
Washington, DC 20036-5339

Re: **Your letter to Advanced BioHealing, Inc.**

Dear Mr. Ravitz:

We are counsel to Advanced BioHealing, Inc. Our client referred to me your January 9, 2008 letter, which you sent on behalf of your client Organogenesis, Inc.

We are reviewing this matter carefully with Advanced BioHealing and will respond to your letter substantively by no later than Friday, January 18.

In the meanwhile please feel free to contact me if there's anything further you would like to discuss.

Very truly yours,

HOLLAND & KNIGHT LLP



Charles D. Tobin

cc: Mr. Kevin Rakin
Michael M. Gaba, Esq.

CDT:hjc # 5049957_v1

Exhibit 3

Arent Fox LLP / Washington, DC / New York, NY / Los Angeles, CA

Arent Fox

January 16, 2008

VIA FACSIMILE AND FIRST CLASS MAIL

Charles D. Tobin, Esquire
Holland & Knight
2099 Pennsylvania Avenue, N.W., Suite 100
Washington, D.C. 20004-4801

Savalle C. Sims

Attorney
202.857.8948 DIRECT
202.857.6395 FAX
sims.savalle@arentfox.com

Re: Advanced BioHealing, Inc.

Dear Chuck:

I write in furtherance of our letter to your client, Advanced BioHealing, Inc. ("Advanced BioHealing") dated January 9, 2008 and this firm's recent discussions with you concerning Advanced BioHealing's recent communications regarding Apligraf and OI's recent Apligraf recall (the "Apligraf Recall").

During our recent discussions, you told us that Advanced BioHealing had ceased disseminating communications regarding the Apligraf Recall ("Advanced BioHealing Communications") while the parties discuss a global resolution of this matter. More specifically, we understood from you that Advanced BioHealing had ceased disseminating the Advanced BioHealing Communications upon receipt of Mr. Ravitz's January 9, 2008 letter to Kevin Rakin, Advanced BioHealing's Chief Executive Officer.

As I shared with you earlier this week, we believe that Advanced BioHealing's dissemination of communications regarding the Apligraf Recall are not limited to communications initiated by Andrew Sole and extend *far* beyond the New York area. As we discussed, Advanced BioHealing's immediate halt of the complained of conduct is of particular importance to OI because Advanced BioHealing's actions are interfering with the Apligraf Recall.

Just today, OI shared with us a troubling communication evidencing that Advanced BioHealing continues to disseminate the Advanced BioHealing Communications despite its representations to the contrary. I refer in particular to the electronic mail message that Carol Gray, an Advanced BioHealing employee sent to one of OI's Apligraf customers located in Richmond, Virginia "***Re Recall: Copy of the Recent Apligraf Recall Letter, Unparalleled Safety Profile of Dermagraft***". Additionally, an Apligraf customer in Michigan informed OI today that she received the enclosed facsimile on January 10, 2008. At a minimum, the enclosed communications evidence that (1) the Advanced BioHealing Communications are emanating from more than a single employee; (2) the Advanced BioHealing Communications are *not* limited to the New York area;

Charles D. Tobin, Esquire

January 16, 2008

Page 2

Arent Fox

and (3) Advanced BioHealing continues to disseminate the Advanced BioHealing Communications despite its interim agreement not to do so.

OI views these latest developments as particularly egregious given your client's assurances that it had ceased and desisted the complained of conduct. Advanced BioHealing's conduct calls into question the spirit in which it has approached the parties' recent settlement discussions. More importantly, we question with new skepticism Advanced BioHealing's reluctance to provide OI with information that it needs to minimize the harm and confusion that Advanced BioHealing has caused to the Apligraf Recall from a public health standpoint.

Clearly, your client's unwritten assurances are no longer sufficient. Accordingly, we request that Advanced BioHealing provide in writing today assurances that it will cease and desist disseminating statements regarding Apligraf and the Apligraf Recall while the parties' settlement discussions are ongoing.

Sincerely,



Savalle C. Sims

Enclosures

cc: James Ravitz, Esquire

Mr. Geoff MacKay

Mr. Patrick R. Bilbo

From: Limor Glazer-Schwam [mailto:limor.glazerschwam@verizon.net]
Sent: Tuesday, January 15, 2008 11:40 PM
To: Stephen Rowe
Subject: FW: Recall: Copy of the Recent Apligraf Recall Letter, Unparalleled Safety Profile of Dermagraft.

Note my response to her shameful behavior.

From: Carol Gray [mailto:cgray@advancedbiohealing.com]
Sent: Monday, January 14, 2008 11:39 PM
To: Limor Glazer-Schwam
Subject: RE: Recall: Copy of the Recent Apligraf Recall Letter, Unparalleled Safety Profile of Dermagraft.

I would like to send my apology to you. I tried to recall any email that was not received as you can see below.

From: Limor Glazer-Schwam [mailto:limor.glazerschwam@verizon.net]
Sent: Monday, January 14, 2008 10:29 PM
To: Carol Gray
Subject: RE: Recall: Copy of the Recent Apligraf Recall Letter, Unparalleled Safety Profile of Dermagraft.

Shame on you.

From: Carol Gray [mailto:cgray@advancedbiohealing.com]

Sent: Monday, January 14, 2008 9:10 PM

Subject: Recall: Copy of the Recent Apligraf Recall Letter, Unparalleled Safety Profile of Dermagraft.

Carol Gray would like to recall the message, "Copy of the Recent Apligraf Recall Letter, Unparalleled Safety Profile of Dermagraft."



A MEMBER OF TRINITY HEALTH

FAX

Date: 1/16/08 Pages: 3
To: Caroline Curtis From: Wound Care Center Lwani
Phone: Phone: (734) 655-3800
Fax: (781) 401-1288 Fax: (734) 655-3810
Re:

☐ Urgent ☒ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

• Comments

per our phone conversation,
this is the faxed notification
we received on 1/10/08.
Thanks
Lwani

1/16/08: Lorraine Getken, RN
OC stated she received this
fax on Jan 10, 9:50

Vision Statement

To be a truly great hospital, providing
comprehensive, coordinated, and compassionate care,
every time to everyone



CONFIDENTIALITY NOTICE: This electronic message and all contents contain information from Trinity Health which may be privileged, confidential or otherwise protected from disclosure. The information is intended to be for the addressee only. If you are not the addressee, any disclosure, copy, distribution or use of the contents of this message is prohibited. If you have received this electronic message in error, please notify us immediately and destroy the original message and all copies.

Organogenesis Inc.
LIVING TECHNOLOGY

100 Das Road, Carson, Massachusetts 01921

✓ Mary Gilbertson's chart

December 27, 2007

Subject: Potential contaminated Apligraf Units manufactured by Organogenesis Inc.

Dear Doctor:

This letter is intended to inform you of important information regarding Apligraf units shipped to you on December 14 or 17, 2007. This involves units from Apligraf Lot Number GS0711.20.01.2A. You have received Apligraf unit(s) from this Lot.

Description of Issue

Apligraf Lot Number GS0711.20.01.2A was reported to have contamination in the agarose nutrient medium of some units received at Organogenesis. Colonies were visually observed within the agarose. Preliminary microbiological testing identified the bacterial contaminant as a gram positive rod (bacillus) organism. A definitive identification of the organism will be provided to you by fax as soon as available.

Product Disposition

According to our records, your procedure date(s) for Apligraf from this Lot has already occurred and the product has likely been applied to a patient(s). If you have not applied the affected unit(s) to a patient, you should return unused product to Organogenesis Inc. for investigation. Information on product return can be obtained by contacting Organogenesis at the number below. Please maintain accurate and complete records of all returns and their disposition.

Clinical Implications

While the unit(s) you have received may not be contaminated, all standard wound care precautions should be used to assure the safety of the patient. If the affected units had been applied to a patient, it is recommended that you monitor the patient closely for any potential adverse events. Organogenesis recommends careful assessment of possible infection by observing for signs and symptoms of infection as well as treatment per your clinical discretion. Treatment options at your clinical

GS0711.20.02.2A

Lot # of

Mary Gilbertson

12/20/07

Page 1 of 2



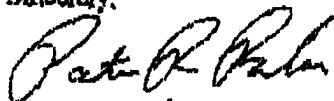
discretion include topical antibiotics, oral antibiotics or Apligraf removal. We hope that this information is helpful in managing care for your patient.

The quality of Apligraf and its safety are of the highest priority to Organogenesis. We are committed to providing complete information in a timely fashion and will contact you for patient follow up and reports of any adverse events that may have resulted subsequent to this Apligraf treatment.

In addition to this faxed letter, we are attempting to contact you by phone to provide information on this Apligraf Lot. Although we will be attempting to contact you by phone today, it will be most efficient if you can contact us at 1 888 432-5232, Option # 2 (Medical Inquiries).

To confirm receipt of this important communication, please sign and fax back this form to us at 781-401-1288.

Sincerely,



Patrick Bilbo
Vice President, Regulatory Affairs
(781) 401-1155

Recipient Signature: _____

Recipient Name: _____

PLEASE RETURN THIS LETTER SIGNED TO FAX #781-401-1288

Exhibit 4

Sims, Savalle

From: charles.tobin@hklaw.com
Sent: Wednesday, January 16, 2008 7:05 PM
To: Sims, Savalle
Cc: Ravitz, James R.; michael.gaba@hklaw.com
Subject: Advanced BioHealing

Savalle,

We have shared your fax of this evening with our client. We do not believe the dissemination is ongoing, and the material you have provided does not reflect that it is.

To be clear on the timeline:

- In response to your initial letter of January 9, the next day, on January 10, Advanced BioHealing instructed its sales representative Andrew Sole in New York to cease communications about the Apligraf recall.
- My firm was engaged on January 10 to assist Advanced BioHealing in this matter.
- On January 11, Advanced BioHealing instructed its entire sales staff to cease communications about the Apligraf recall.
- On January 14, a followup reminder was given to the entire sales staff.

I had previously offered to provide you with written assurances that Advanced BioHealing has instructed its entire sales staff to refrain from disseminating information about the Apligraf recall. I am doing so now. That instruction has been given, and repeated, as detailed above.

We appreciate the documents you sent with your letter. As you know, we have been asking for two days for Organogenesis to provide specifics instead of vague reports about alleged "ongoing" communications.

The documentation you presented yesterday, as well as the attachments to your letter of today, appear to reflect activity that occurred last week and not current activity. As far as the email you shared tonight, it appears to us that on January 14, this sales rep – instead of disseminating the recall notice, as your letter suggests – was trying to "recall" an earlier email in which she may have disseminated the Apligraf recall notice (her original email is not in the materials that you sent, only correspondence about her effort to "recall" it).

Advanced BioHealing has represented to counsel, and we trust our client's representation, that no further disseminations are being, and that none will be made as we continue to investigate. We are reviewing your settlement proposal. We will continue to work with you in good faith through these issues.

Chuck

Holland + Knight

Charles D. Tobin

Partner
Holland & Knight LLP
2099 Pennsylvania Avenue N.W.
Washington, DC 20006
Main (202) 955-3000
Direct (202) 419-2539

1/22/2008

Fax (202) 955-5564
Email ctobin@hklaw.com
www.hklaw.com

NOTICE: This e-mail is from a law firm, Holland & Knight LLP ("H&K"), and is intended solely for the use of the individual(s) to whom it is addressed. If you believe you received this e-mail in error, please notify the sender immediately, delete the e-mail from your computer and do not copy or disclose it to anyone else. If you are not an existing client of H&K, do not construe anything in this e-mail to make you a client unless it contains a specific statement to that effect and do not disclose anything to H&K in reply that you expect it to hold in confidence. If you properly received this e-mail as a client, co-counsel or retained expert of H&K, you should maintain its contents in confidence in order to preserve the attorney-client or work product privilege that may be available to protect confidentiality.